FEDERAL SECURITY AGENCY

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

141–275

DRUGS AND DEVICES

The cases reported herewith, commenced prior to June 30, 1940, were instituted in the United States District Courts by the United States attorneys acting upon reports submitted by direction of the Secretary of Agriculture; and those commenced on and after that date were similarly instituted upon reports submitted by direction of the Federal Security Administrator.

WAYNE COY, *Acting Administrator, Federal Security Agency.*

Washington, D. C., February 24, 1941.

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DRUGS AND DEVICES ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED ACCORDING TO DIRECTIONS AND/OR BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS

SEDATIVES, PAIN RELIEVERS, AND HEADACHE REMEDIES

141. Misbranding of Bromo-Citra. U. S. v. 74 Cartons and 22 Cartons of Bromo-Citra. Default decrees of condemnation and destruction. (F. D. C. Nos. 1656, 1831. Sample Nos. 55485–D, 72169–D.)

This product contained acetanilid, sodium bromide, caffeine, sodium chloride, sodium bicarbonate, and citric and tartaric acids. It would be dangerous to health when used in the dosage or with the frequency prescribed, recommended, or suggested in the labeling. Its labeling was further objectionable for the reasons indicated hereinafter.

On March 22 and April 29, 1940, the United States attorneys for the Eastern District of Michigan and the District of Nebraska filed libels against 74 cartons of Bromo-Citra at Detroit, Mich., and 22 cartons of the product at Kenesaw, Nebr., alleging that the article had been shipped in interstate commerce on or about January 15 and February 14, 1940, by the Drexel Co. from Elgin, Ill.; and charging that it was misbranded.

The product in both shipments was alleged to be misbranded in that it was dangerous to health when used in the dosage or with the frequency prescribed, recommended, or suggested in the labeling; and in that the labeling failed to reveal facts material with respect to consequences which might result from the use of the article under the conditions of use prescribed in the labeling. Misbranding was alleged with respect to both shipments for the reason that the name "Bromo-Citra" was false and misleading since it indicated that the article was derived from the ingredient sodium bromide; whereas the principal ingredient was acetanilid. Misbranding was alleged with respect to both shipments for the further reason that the representation in the labeling that the average net weight was 100 grams was false and misleading since the net weight of sample vials taken from the shipments showed an average of 6.73 grams and 7.12 grams, respectively.

The shipment of January 15, 1940, to Detroit, Mich., was alleged to be misbranded further in that the representation in the labeling that each ounce contained 16 grains of sodium bromide, was false and misleading since each ounce contained more than represented, namely, not less than 18.36 grains of sodium bromide.

The shipment of February 14, 1940, to Kenesaw, Nebr., was alleged to be misbranded further in that its labeling bore representations that it was to be used as a relief for the discomfort due to simple headache, neuralgia, overindulgence, i. e., too much food, drink, or smoking; that the dose consisted of the contents of the vial in ½ glass of water, that not more than 3 doses should be taken within a period of 24 hours, which were false and misleading since they created the impression that the article constituted an appropriate treatment in such conditions; whereas it was not a safe and appropriate remedy but was a dangerous drug.

On May 14 and June 28, 1940, no claimant having appeared, judgment of condemnation were entered and the product was ordered destroyed.

142. Misbranding of Koenig's Nervine. U. S. v. 45 Bottles of Koenig's Nervine. Default decree of condemnation and destruction. (F. D. C. No. 1529. Sample No. 89142–D.)

This product contained sodium, potassium, and ammonium bromides, extracts of plant material (including valerian), glycerin, alcohol, and benzoic acid. It would be dangerous to health when used as directed, prescribed, recommended, or suggested in its labeling. The labeling was further objectionable since it created the impression that the article was an appropriate treatment for the conditions for which it was recommended and because of failure to reveal the consequences which might result from its use.

On February 29, 1940, the United States attorney for the Eastern District of Michigan filed a libel against 45 bottles of Koenig's Nervine at Detroit, Mich., alleging that the article had been shipped in interstate commerce on or about February 15, 1940, by the Koenig Medicine Co. from Chicago, Ill.; and charging that it was misbranded.

The article was alleged to be misbranded in that its labeling bore representations that it was indicated as a sedative in common nervousness, sleeplessness, restlessness, nervous irritability, functional nervous disturbances, and headache due to common nervousness, and bore directions that the dose for an adult was ½ to ¾ tablespoonful in ½ glass of water 3 times a day, that it should preferably be taken after the noonday and evening meals and at bedtime, that the dose for children 12 to 18 years old was one-half the adult dose, that ½ to ¾ tablespoonful should be taken in ½ glass of water after the evening meal for sleeplessness due to nervousness and that the dose should be repeated before retiring if needed; that some individuals are more easily affected by the sedative action of the product and the dose should be regulated accordingly; that if sleepiness occurs during the day the dose should be reduced; that for the conditions indicated it should not be necessary to use the product continuously for long periods and that in cases of persistent nervousness a physician should be consulted; that the product had been used for 50 years and contained no opiates; that some persons are peculiarly susceptible to bromides and on those persons their use might produce a rash; that if such rash appeared the use of the product should be discontinued until the rash disappeared, when its use might be resumed in smaller doses and gradually increased to the point of tolerance; that a very large percentage of nervous disorders are due to a strained, overworked, and irritable condition of